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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/935,487 | 08/23/2001 | Robert F. Rioux | BSC-187 (1002/257) | 1401 |

21874 7590 01/23/2007
EDWARDS & ANGELL, LLP
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| EXAMINER | |
|---|---|
| PELLEGRINO, BRIAN E | |
| ART UNIT | PAPER NUMBER |
| 3738 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/23/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/935,487 | RIOUX ET AL. | |
| | Examiner | Art Unit | |
| | Brian E Pellegrino | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 November 2006* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4 and 6-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *p.2 of 105 of 8/06* 6) ☐ Other:
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Yachia et al. (5246445). Evard et al. illustrates (Fig. 2' ) a coil segment with a middle portion **14** spaced from the proximal and distal windings and has a diameter less than the proximal and distal ends. Evard et al. disclose a covering or what can be interpreted as "webbing" such that **a portion** or the entire device is encapsulated or *covered* by the covering, page 33, lines 5-8. It can be interpreted from the disclosure of Evard on page 14, lines 22-25 that these coverings inhibit ingrowth of body tissue. Evard also discloses the coil can be a biocompatible wire made from steel or nickel titanium, page 34, lines1-3. The Examiner is also interpreting the limitation "webbing between the windings" to be present in the Evard device since the covering is over the windings, it can be considered between the windings. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly, the device is capable of being positioned coaxially within the body lumen of a patient. However, Evard fails to disclose the distance between the windings or a cross-sectional area of 0.0079mm$^2$ to 0.785 mm$^2$ of the wire. Yachia et al. teach a cross-sectional area of 0.0079mm$^2$ to 0.785 mm$^2$ col. 4, lines 44,45. Yachia et al. also teach (Fig. 1a) a stent with hooks **3** at both the

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proximal and distal ends of the coil body for connection to a delivery system, col. 6, lines 13-16. Yachia also teaches to have a spacing between windings of about 0.1-2mm. It would have been obvious to one of ordinary skill in the art to incorporate hooks at both proximal and distal ends of a stent as taught Yachia et al. in the device of Bosley such that the vessel apparatus does not dislodge from the instrument used to implant it and also to use a wire with the cross-sectional area and the spacing between windings taught by Yachia in the prosthesis of Evard such that it provides the flexibility necessary and the proper amount of coverage against the vessel wall implanted in.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Yachia et al. '445 and further in view of Hachtman et al. (5645559). Evard as modified by Yachia is explained supra. However, Evard in view of Yachia do not disclose a low durometer silicone within the range of 0-60D. Evard does disclose that silicone sleeves can be placed on stents, page 17, lines 21-24. Hachtman et al. also teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the silicone on Evard's stent as modified by Yachia such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

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***Response to Arguments***

Applicant's arguments filed 11/7/06 have been fully considered but they are not persuasive. Applicant argues that the covering disclosed by Evard is not "between the spaced windings" since it is mounted on the windings as Applicant states. As mentioned in the rejection the Examiner interpreted the terms encapsulate "**a portion**" as to cover partially. The Examiner notes that the claims do not recite that the polymer material entirely surrounds the coil segments. Evard clearly meets this limitation since the material is over the coil segments and the space between the coil windings. The Examiner interpreted the space between the windings to encompass the area above. The claims do not require the polymer material to extend into the space between the windings as Applicant is attempting to argue. Claims are given their broadest reasonable interpretation. See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant states that Yachia does not disclose a covering or webbing. However, the Examiner only used the reference as a teaching for the spacing between the windings of a coil device for implantation. The fact that Yachia fails to disclose a covering is irrelevant since Evard already discloses the use of a "webbing". Since the coil of Evard is to be implanted, one of ordinary skill in the art would look to finding the

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dimensions of the spacing to use for delivery purposes as found in Yachia and thus it is proper to combine the references.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 8:30am to 6pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino

